K033373

NOV 1 3 2003

EXHIBIT # 9

510(k) Summary

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Tyco Healthcare/Kendall
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: October 17, 2003

1. Contact Person

David A. Olson
Vice President, Regulatory Affairs
(508) 261-8530

2. Name of Medical Device

Trade Name:	Monoject Insulin Syringe
Classification Name:	Piston Syringe
Common or Usual Name:	Insulin Syringe

3. Identification of Legally Marketed Device

The proposed Kendall Monoject® Insulin Syringe are substantially equivalent in intended use, design and function to Becton Dickinson's Ultra - Fine™ II Insulin Syringe, 510(k) No. K024112 and the Kendall Monoject Insulin Syringe, 510(k) No. K991758.

4. Device Description

These devices are sterile, single use, disposable hypodermic syringes with permanently affixed hypodermic needles. Monoject Insulin Syringes consist of a syringe barrel, a plunger rod, and a hypodermic needle permanently affixed to the tip of the syringe with epoxy. Monoject Insulin Syringes are available in 1.0 cc (100 units), 0.5 cc (50 Units) and 0.3 cc (30 units) syringe capacities with a 30g x 5/16 inch needle.

5. Device Intended Use

The proposed device is intended for the subcutaneous injection of U-100 Insulin.

6. Summary of Technological Characteristics

The only design change being incorporated into current Monoject Insulin Syringes compared to currently marketed Monoject Insulin Syringes is the addition of a new needle size – 31 Gage x 5/16" Length. This needle is of smaller diameter than the current Monoject 30 Gage x 5/16" Length insulin needle. All other aspects are identical to current Monoject Insulin Syringes. Monoject Insulin Syringes conform to International Standard ISO 8537:1991(E) "Sterile single-use syringes, with or without needle, for insulin", except in regard to the presence of the 31 gage (0.26 mm OD.) needle which is not contained in the standard and in regard to certain marking requirements.

The new Monoject 31 Gage x 5/16" insulin needle is identical in materials, design and intended use to 31 Gage x ½ " insulin needles currently marketed by Becton-Dickinson.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2003

Tyco HealthCare
Mr. David A. Olson
Vice President, Regulatory Affairs
Kendall
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K033373
Trade/Device Name: Monoject® Insulin Syringe
Regulation Number: 880.5570, 880.5860
Regulation Name: Hypodermic Single Lumen Needle Piston Syringe
Regulatory Class: II
Product Code: FMI
Dated: October 17, 2003
Received: October 22, 2003

Dear Mr. Olson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

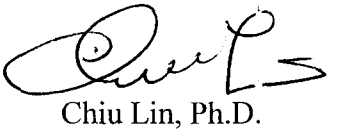
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): k033373

Device Name: Monoject® Insulin Syringe

Indications for Use: Kendall Monoject® Insulin Syringes are intended for subcutaneous injection of U-100 insulin.

Please Do Not Write Below This Line – Continue On Another Page If Needed

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter ✓
Use_____
(Per 21 CFR 801.109)

Patricia Cucuzzella

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033373